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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/375,514	08/17/1999	JOHN C. REED	3335-075-55-	5198

7590 12/18/2002
Laura A. Coruzzi
PENNIE & EDMONDS LLP.
1155 Avenue of the Americas
New York, NY 10036-2711

EXAMINER

SCHMIDT, MARY M

ART UNIT PAPER NUMBER

1635

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/375,514	Applicant(s) Reed
Examiner Mary Schmidt	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 23, 2002, and October 22, 2001
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-69
- 4a) Of the above, claim(s) _____ is/are pending in the application.
- 5) ☒ Claim(s) 53 is/are withdrawn from consideration.
- 6) ☒ Claim(s) 54-69 is/are allowed.
- 7) ☐ Claim(s) _____ is/are rejected.
- 8) ☐ Claims _____ is/are objected to.
- _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug 17, 1999 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Drawings

1. The drawing informalities noted in Paper No. 18, mailed on 6/20/01, must now be corrected. Correction can only be effected in the manner set forth in the above noted paper.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 54, 56 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is indefinite for the language in line 2, "encoding *the* human bcl-2", since a bcl-2 has not been previously specified by context or by circumstance in the claim, and further, it is not clear to one of skill in the art that there is only one possible variant of the human bcl-2 gene. Similarly, claim 56 is indefinite for the language in line 2, "*the* human bcl-2". Claim 57 depends from claim 56, and is thus included in the rejection. In the absence of a specific identification of the bcl-2 gene, such as the SEQ ID NO., it is proper to use the functional word "a" to introduce the noun "bcl-2 gene".

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4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 54-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 54-69 as amended in the amendment filed 10/22/01, remain drawn to a broad scope of any human bcl-2 gene sequence, where the anticodon oligomer targets any pre-mRNA encoding human bcl-2, splice acceptor site or splice donor site of the pre-mRNA encoding human bcl-2, or any 5'-untranslated region of the human bcl-2 mRNA.

The specification as filed teaches SEQ ID NO:19 as the human bcl-2 gene sequence (like in claim 22 of U.S. Patent 5,831,066). The specification as filed does not teach by way of sequence structure any other possible human bcl-2 gene sequences, coding or pre-mRNA sequences. The target gene sequence for an antisense oligonucleotide, such as those instantly claimed to human bcl-2, are considered "essential material" as per the meaning in MPEP 608.01(p)(1)(A) since the knowledge of the specific nucleic acid sequence of the target gene sequence is necessary for design of the antisense sequence(s) thereto. Therefore, since the specification as filed has not taught any target human bcl-2 gene sequences by way of nucleic acid sequence structure, other than instant SEQ ID NO:19, one of skill in the art would not have

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recognized that applicant was in possession of any other possible target human bcl-2 gene sequences at the time the invention was made.

6. Claim 53 is allowed. The prior art did not teach nor fairly suggest the nucleic acid sequence from 18-35 bases comprising the nucleotide sequence of instant SEQ ID NO:17.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt
December 14, 2002

Mary Schmidt